105 CMR 700.000: IMPLEMENTATION OF M.G.L. c. 94C

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700.001: Definitions

For the purpose of 105 CMR 700.000, the following definitions apply, in addition to those definitions appearing in M.G.L. c. 94C, § 1, unless the context or subject matter requires a different meaning.

Administer means the direct application of a controlled substance whether by injection, inhalation, ingestion or any other means to the body of a patient or research subject by:

(1) A practitioner or

(2) A registered nurse or licensed practical nurse at the direction of a practitioner in the course of his professional practice, or

(3) An ultimate user or research subject at the direction of a practitioner in the course of his professional practice.

Agent means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser; except that such term does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

Ambulance Service means an entity licensed as an ambulance service by the Department in accordance with M.G.L. c. 111C, § 6 and 105 CMR 170.000.

Bureau means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice or its successor agency.

Certified Nurse Midwife means a nurse authorized to practice as a nurse midwife by the Board of Registration in Nursing, as provided for in M.G.L. c. 112, §§ 80B and 80C and regulations of the Board of Registration in Nursing, 244 CMR 4.00 *et seq*., most specifically 244 CMR 4.11 through 4.27.

Chemical Analyst means a person engaged in the qualitative or quantitative analysis of controlled substances within a scientific laboratory.

Chronic Patient means, for the purposes of 105 CMR 700.000 only, a person diagnosed by a physician as having a physical or mental illness characterized by slow progress and long continuance.

Commissioner means the Commissioner of Public Health or his duly authorized agent.

Community Program means any community residential or day program serving mentally ill or mentally retarded persons which is funded, operated or licensed by the Massachusetts Department of Mental Health or Department of Mental Retardation, with the exception of programs funded under Title XIX of the Social Security Act.

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Controlled substance means a drug, substance, or immediate precursor in any schedule or class referred to in M.G.L. c. 94C or 105 CMR 700.000.

Compounding means in the definition of "Manufacture", compounding a controlled substance other than:

(1) By a practitioner or,
(2) By a pharmacist subject to a prescription.

Deliver means to transfer, whether by actual or constructive transfer, a controlled substance from one person to another, whether or not there is an agency relationship.

Dental Hygienist means a person registered by the Board of Registration in Dentistry pursuant to M.G.L. c. 112, § 51.

Department means the Department of Public Health.

Department of Mental Health means the Massachusetts Department of Mental Health.

Department of Mental Retardation means the Massachusetts Department of Mental Retardation.

Depressant or stimulant substance means:

(1) A drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or any derivative of barbituric acid which the United States Secretary of Health, Education and Welfare has by regulation designated as habit forming; or
(2) A drug which contains any quantity of amphetamine or any of its optical isomers; any salt of amphetamine or any salt of an optical isomer of amphetamine; or any substance which the United States Attorney General has by regulation designated as habit forming because of its stimulant effect on the central nervous system; or
(3) Lysergic acid diethylamide; or
(4) Any drug except marihuana which contains any quantity of a substance which the United States Attorney General has by regulation designated as having a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

Dispense means to deliver a controlled substance to an ultimate user or research subject or to the agent of an ultimate user or research subject by a practitioner or pursuant to the order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary for such delivery.

Distribute means to deliver other than by administering or dispensing a controlled substance.

Drug means:

(1) Substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary or any supplement to any of them:
(2) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals;
(3) Substances, other than food, intended to affect the structure or any function of the body of man and animals; or
(4) Substances intended for use as a component of any article specified in 105 CMR 700.001(M)(1) through 700.001(M)(3), exclusive of devices or their components, parts or accessories.

EMS First Responder (EFR) means a person certified as an EFR by the Department, in accordance with M.G.L. c. 111C, § 9 and 105 CMR 170.000, and authorized to administer controlled substances pursuant to his or her certification and the Statewide Treatment Protocols.

EMS First Response Service (EFR Service) means an entity licensed as an EFR service by the Department in accordance with M.G.L. c. 111C, § 6 and 105 CMR 170.000.

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Emergency Medical Technician (EMT) means a person certified by the Department, pursuant to M.G.L. c. 111C, § 9 and 105 CMR 170.000, in accordance with his or her level of training, to administer controlled substances pursuant to his or her training and the Statewide Treatment Protocols. The term EMT shall include EMT-Basic and the ALS levels of EMT-Intermediate and EMT-Paramedic as defined in 105 CMR 170.000.

First Responder means a First Responder as defined in M.G.L. c. 111, § 201 and 105 CMR 171.000, and who is authorized to administer controlled substances in accordance with 105 CMR 171.000, his or her training thereunder and the Statewide Treatment Protocols.

Fluoride Program Monitor means a dental assistant, school teacher, school aide or school volunteer.

Health Facility means:

(1) A hospital, hospital pharmacy, long-term care facility, or clinic or institution for unwed mothers, infirmary maintained in a town, convalescent home, nursing home or charitable home for the aged, licensed or maintained by the Department; or

(2) A public medical institution as defined in M.G.L. c. 118E, § 2; or

(3) Any institution licensed or maintained by the Department of Mental Health; or

(4) Any hospital, long-term care facility or clinic maintained by the Commonwealth.

(5) Any ambulance service licensed by the Department to provide Advanced Life Support services.

Home Care Setting means any place where a person resides which is not licensed or funded by the Commonwealth to provide institutional care or custody. Home care settings include, but are not limited to the following:

(1) an individual's private home;

(2) community residences or group homes licensed or funded by an agency of the commonwealth;

(3) shelters and day centers for the homeless; and

(4) hospice settings which are approved by the Department and which are not licensed to provide acute care or operated by a hospital so licensed.

Hospital means any institution, however named, whether conducted for charity or for profit, which is advertised, announced, established or maintained for the purpose of caring for persons admitted thereto for diagnosis, medical, surgical or restorative treatment which is rendered within said institution.

Immediate Precursor means a substance which the Commissioner has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

Implantable Infusion Pump means a device that is intended to be implanted in the human body for the purpose of delivering a controlled flow of drug(s).

Institutionalization means admission on an inpatient basis to in one of the following settings:

(1) long-term care facilities, as that term is defined in 105 CMR 700.000;

(2) hospitals, as that term is defined in 105 CMR 700.000.

Isomer means the optical isomer, except that wherever appropriate it shall mean the optical, position or geometric isomer.

Labeling means in the definition of "manufacture", labeling or relabeling other than:

(1) By a practitioner, or

(2) By a pharmacist.

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Long-term Care Facility means any institution whether conducted for charity or profit, which is advertised, announced or maintained for the express or implied purpose of providing three or more individuals admitted thereto with long-term resident, nursing, convalescent or rehabilitative care; supervision and care incident to old age for ambulatory persons; or retirement home care for elderly persons. For the purposes of 105 CMR 700.000 only, long-term care facility shall include hospitals which are licensed solely to provide chronic and/or rehabilitative care, state schools for mentally retarded persons, state hospitals for mentally ill persons, convalescent or nursing homes, rest homes, infirmaries maintained in towns and charitable homes for the aged.

(1) "Convalescent or nursing homes, rest homes, infirmaries maintained in a town, and charitable homes for the aged" shall have the same meanings as those terms defined in M.G.L. c. 111, § 71.

(2) "Long-term Care" means care of significant duration, as distinguished from acute short-term care provided in a general hospital, and shall not include care provided in a hospital licensed to provide acute care.

Manufacture means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, including any packaging or repackaging of the substance or labeling or relabeling of its container except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging or labeling of a controlled substance:

(1) By a practitioner as an incident to his administering a controlled substance in the course of his professional practice, or

(2) By a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

Marihuana means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; and resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture or preparation of the mature stalks, except the resin extracted therefrom, fiber, oil or cake of the sterilized seed of the plant which is incapable of germination.

Medication Order means a written order for medication entered on a patient's medical record maintained at a hospital or other inpatient health facility and is dispensed for immediate administration to the ultimate user by an individual authorized by M.G.L. c. 94C to administer such medication.

Narcotic drug means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(2) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in 105 CMR 700.001(T)(1), but not including the isoquinoline alkaloids of opium;

(3) Opium poppy and poppy straw;

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

National Association of Boards of Pharmacy (NABP) Number means a unique seven digit number issued by the National Council for Prescription Drug Programs (NCPDP).

National Drug Code Number (NDC) means a nationally recognized standard which identifies drug products using a unique number, issued by the United States Food and Drug Administration, involving three components. The first component identifies the drug manufacturer ("LABELER NO.") the second identifies the product "PRODUCT NO.", the third

identifies the package size "PKG".

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Non-self-medicating means personally taking or applying prescription medication in the manner directed by the prescribing practitioner, with more than minimal assistance or direction by the program staff, as determined in accordance with procedures and criteria established by the Department of Mental Health or Department of Mental Retardation and approved by the Department of Public Health.

Nurse Practitioner means a nurse authorized to practice as a nurse practitioner by the Board of Registration in Nursing as provided for in M.G.L. c. 112, § 80B and regulations of the Board of Registration in Nursing, 244 CMR 4.00 *et seq.*, most specifically 244 CMR 4.11 through 4.27.

Opiate means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under M.G.L. c. 94C, § 2, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts, dextromethorphan. It does include its racemic and levorotatory forms.

Opium Poppy means the plant of the species Papaver somniferum L., except its seeds.

Oral Prescription means an oral order for medication which is dispensed to or for an ultimate user, but not including an order for medication which is dispensed for immediate administration to the ultimate user by a practitioner, registered nurse, or practical nurse.

Packaging means in the definition of "manufacture", packaging or repackaging a controlled substance other than:

(1) By a practitioner or,
(2) By a pharmacist.

Patient Identifier means a positive identification of the person who is receiving the prescription for a drug in Schedule II from the pharmacy and consists of one of the following:

(1) a valid driver's license number;
(2) a valid military identification card number; or
(3) the number of a valid identification card issued pursuant to M.G.L. c. 90, § 8E or similar statute of another state or the federal government. In the case of a recipient less than 18 years of age with no such identification the patient identifier may be that of the recipient's parent or guardian. In the case of an animal, the patient identifier may be that of the owner.

Person means individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.

Physician Assistant means a physician assistant authorized to practice by the Board of Registration of Physician Assistants, as provided for in accordance with M.G.L. c. 112, § 9I and authorized to prescribe by St. 1991, c. 445, § 7(g) in accordance with regulations of the Board of Registration of Physician Assistants, 263 CMR 2.00 *et seq*.

Poppy Straw means all parts, except the seeds of the opium poppy, after mowing.

Practical nurse means a nurse who is licensed pursuant to the provisions of M.G.L. c. 112, § 74A.

Practitioner means:

(1) A physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth;
(2) A pharmacy, hospital or other institution registered to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in the commonwealth.
(3) An optometrist authorized by M.G.L. c. 112, §§ 66 and 66B and registered pursuant to M.G.L. c. 94C, § 7(h) to utilize and prescribe topical therapeutic pharmaceutical agents, as defined in M.G.L. c. 112, § 66B, in the course of professional practice in the commonwealth.

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Private School means the board of trustees, board of directors or comparable board responsible for operating a private elementary or secondary school program.

Prescription Drug means any and all drugs upon which the manufacturer or distributor has, in compliance with federal laws and regulations, placed the following: "Caution, Federal law prohibits dispensing without prescription."

Psychiatric Nurse means a nurse authorized to practice as a psychiatric nurse mental health clinical specialist by the Board of Registration in Nursing, as provided for in M.G.L. c. 112, § 80B and regulations of the Board of Registration in Nursing, 244 CMR 4.00 *et seq.*, most specifically 244 CMR 4.11 through 4.27.

Registered Individual Practitioner shall mean a physician, dentist, veterinarian, podiatrist, certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant who is registered pursuant to 105 CMR 700.004.

Registered Nurse means a nurse who is registered pursuant to the provisions of M.G.L. c. 112, § 74.

Registrant means a person who is registered pursuant to any provision of M.G.L. c. 94C.

Registration means unless the context specifically indicates otherwise such registration as is required and permitted only pursuant to the provisions of M.G.L. c. 94C.

Registration Number means the unique registration number required with respect to a practitioner by, and assigned to a practitioner by, the Bureau of Narcotics and Dangerous Drugs or by the Department of Public Health or both.

Researcher means a person who engages in or conducts research involving substances, whether controlled or not, which are being used or are to be used on humans.

Sample Medication for the purpose of 105 CMR 700.000 shall mean a unit of prescription drug distributed by the manufacturer or distributor to practitioners in the original package from the manufacturer, not repackaged and given free of charge to patients. Such medications shall include but not be limited to those medications dispensed as part of an indigent patient drug program.

Schedule means the list of controlled substances established by the Commissioner pursuant to the provisions of M.G.L. c. 94C, § 2 for purposes of administration and regulation.

School means a public or private elementary or secondary school, or day care center or group care facility licensed by the Office for Children in accordance with M.G.L. c. 28A, § 10.

School District means the local educational agency, which includes the school committee, board of trustees, educational collaborative board, or other public entity responsible for operating a public elementary or secondary school program.

Scientific Laboratory means a facility maintained primarily for the analysis or examination of controlled substances or their precursors, and which is not a facility or part of a facility otherwise registered to manufacture, distribute, dispense or possess controlled substances.

Self-medicating means personally taking or applying prescription medication in the manner directed by the prescribing practitioner, with no more than minimal assistance or direction from program staff, in accordance with procedures and criteria established by the Department of Mental Health or Department of Mental Retardation and approved by the Department of Public Health.

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Statewide Treatment Protocols means the Emergency Medical Service Pre-hospital Treatment Protocols approved by the Department for application statewide in accordance with M.G.L. c. 111C and 105 CMR 170.000.

Supervising Physician means a physician who provides supervision to a physician assistant in accordance with M.G.L. c. 112, §§ 9C through 9H, or who provides supervision to a certified nurse midwife, a nurse practitioner or psychiatric nurse mental health clinical specialist as provided for in 244 CMR 4.05(9) (Board of Registration in Nursing).

Teacher means a person who conducts teaching activities using controlled substances in a teaching institution accredited by the Commission on Institutions of Higher Education.

Tetrahydrocannabinol means tetrahydrocannabinol or preparations containing tetrahydrocannabinol excluding marihuana except when it has been established that the concentration of delta-9 tetrahydrocannabinol in said marihuana exceeds 2½%.

Ultimate User means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

Universal Claim Form (UCF) means a nationally recognized standard form developed by the National Council for Prescription Drug Programs, used for billing prescription drug claims to insurance plans and available through the pharmacy's local wholesaler.

Written Prescription means a written order for medication which is dispensed to or for an ultimate user, but not including an order for medication which is dispensed for immediate administration to the ultimate user by a practitioner, registered nurse or practical nurse.

700.002: Schedules of Controlled Substances

The following schedules of controlled substances are established:

(A) Schedule I. Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.11.

(B) Schedule II. Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.12.

(C) Schedule III. Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.13.

(D) Schedule IV. Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.14.

(E) Schedule V. Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.15.

(F) Schedule VI. Schedule VI shall consist of all prescription drugs, which are not included in any other schedule established by the Commissioner.

700.003: Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)

(A)(1) An EMT-Paramedic, or an EMT-Paramedic student as part of his or her participation in a Department-approved Paramedic training program, may administer only those controlled substances, in quantity and kind, that are necessary for the performance of his or her duties;

(2) An EMT-Intermediate, EMT-Intermediate student as part of his or her participation in a Department-approved Intermediate training program, EMT-Basic or EFR may administer only those controlled substances in Schedule VI for which he or she has been approved by the Department and that are necessary for the performance of his or her duties;

(3) Administration of controlled substances by an EMT, EMT-Paramedic student, EMT-Intermediate student or EFR is also subject to the following conditions:

(a) The ambulance service or EFR service for which the individual serves, shall be registered in accordance with 105 CMR 700.004 for the appropriate controlled substances;

(b) The ambulance service or EFR service shall maintain a current listing of names of its employees and volunteers who are authorized to administer controlled substances;

(c) The EMT, EMT-Paramedic student, EMT-Intermediate student or EFR shall perform only those functions for which he or she is authorized by, and trained in accordance with 105 CMR 170.000;

(d) Administration of controlled substances shall be conducted:

1. pursuant to the order of a practitioner and the Statewide Treatment Protocols; and
2. in accordance with 105 CMR 170.000 and the provisions of the Statewide Treatment Protocols.

(B) Dental hygienists and fluoride program monitors employed by or affiliated with a registered school may administer fluoride tablets or fluoride mouth rinse to school children aged three through 18 provided that:

(1) The school has registered with the Department by sending a letter of intent to administer fluoride treatments to the Division of Dental Health and by providing whatever further information the Commissioner may require; and

(2) The child's parent or guardian has been informed in writing of the nature, dose and effects of fluoride tablets and mouthrinse, and has consented in writing to the administration of fluoride tablets or mouthrinse on behalf of the child; and

(3) The tablets or mouthrinse is administered in accordance with the order of a physician or dentist employed by or associated with a local Board of Health or school; and

(4) The fluoride program monitor has been trained to administer and store fluoride tablets and mouthrinse in accordance with a training program designed by the Commissioner; and

(5) All fluoride mouthrinse and tablets possessed by the registered school are stored securely under lock and key; and

(6) The registered school maintains such records and files such reports concerning the fluoride program as the Commissioner may require.

(C) A certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may issue written prescriptions and medication orders for Schedule II through VI controlled substances, provided that the following requirements are met:

(1) The certified nurse midwife, nurse practitioner and psychiatric nurse meets all requirements set forth in regulations established by the Board of Registration in Nursing, 244 CMR 4.00 *et seq*. and M.G.L. c. 112, § 80B, 80C, 80E, and 80F.

(2) The physician assistant meets all requirements set forth in regulations established by the Board of Registration of Physician Assistants, 263 CMR 2.00 *et seq.* and M.G.L. c. 13, § 10B and M.G.L. c. 112, §§ 9C through 9K.

(3) The certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant registers with the Department's Division of Food and Drugs, in accordance with 105 CMR 700.004 and with the Drug Enforcement Administration, in accordance with 21 CFR 1300.

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(4) The certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant practices in accordance with written guidelines governing the prescription of medication mutually developed and agreed upon by the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant and a supervising physician pursuant to regulations promulgated under M.G.L. c. 112, §§ 80B, 80C, 80E and 80G and M.G.L. c. 112, § 9E that describes the methods to be followed in managing a health care situation or in resolving a health care problem. 105 CMR 700.03(C)(4)(a) and (b) will remain in full force and effect until such time as regulations are promulgated by the Board of Registration in Nursing in accordance with M.G.L. c. 112, §§ 80B, 80C, 80E and 80G and by the Board of Registration of Physician Assistants in accordance with M.G.L. c. 112, § 9E.

(a) Such guidelines for the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant shall address, but need not be limited to, such issues as frequency of medication review by the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant and the supervising physician; review of initial prescriptions or changes in medication by the supervising physician; procedures for initiating intravenous solutions; and limits, if any, on the types of medication to be prescribed, the quantity and duration of prescriptions and the issuance of refill prescriptions.

(b) In the case of a Schedule II drug as defined in 105 CMR 700.002, a prescription shall be reviewed by a supervising physician within 72 hours of issuance.

(5) All prescriptions issued by the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant are consistent with the scope of practice as defined by 244 CMR 4.26 for nurses practicing in the expanded role and 263 CMR 2.00 for physician assistants.

(6) The certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may order controlled substances in Schedule VI from a drug wholesaler, manufacturer, laboratory or distributor. For the purpose of dispensing medication in Schedules II-V for immediate treatment, the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may obtain such medication only as supplied by the supervising physician or obtained through a written prescription for the patient.

(7) A certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may issue oral prescriptions in accordance with M.G.L. c. 94C, § 20, provided that the person issuing the prescription clearly identifies his or her name and professional designation to the pharmacist and provides his or her registration number, work address, phone number, and the name of the supervising physician. An oral prescription shall be followed up with a written prescription by the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant to be provided to the pharmacist or postmarked within a period of not more than seven days or such shorter period as required by federal law, in accordance with M.G.L. c. 94C, § 20.

(8) A certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may prescribe controlled substances for a patient in a health facility or other setting through use of written medication orders entered on the patient's medical record maintained at the facility, provided that such written orders meet all applicable provisions of 105 CMR 700.000.

(D) Persons specified in 105 CMR 700.003(D) may administer epinephrine or atropine, pralidoxime chloride or other designated nerve agent antidotes in a life threatening emergency, where medical professionals are not readily available, in accordance with any applicable Department protocols and the following:

(1) To the extent authorized by 105 CMR 700.003(D), the following persons may administer epinephrine or nerve agent antidotes

(a) a first responder may administer epinephrine in accordance with 105 CMR 171.000 and the Statewide Treatment Protocols;

(b) a public employee of or volunteer to a municipality or an agency, department or authority of the Commonwealth ("agency"), whose function includes emergency preparedness and response and who is designated by a municipality's or agency's medical director pursuant to 105 CMR 700.003(6)(b) ("authorized public employee"), may administer epinephrine as well as atropine, pralidoxime chloride and other nerve agent antidotes approved by the Department ("nerve agent antidotes") to another authorized public employee; and

(c) an authorized employee of or volunteer to a facility or program funded, operated or licensed by a municipality or agency may administer epinephrine to individuals served by such a program or facility ("program");

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(2) A municipality or agency may approve administration of epinephrine or nerve agent antidotes by authorized public employees, and a municipality or agency may approve administration of epinephrine by employees or volunteers of a program, provided that the municipality or agency registers with the Department in accordance with 105 CMR 700.004. This registration requirement shall not apply to:

(a) a municipality or agency registered under 105 CMR 700.004(A)(2)(a) through (A)(2)(t);

(b) a school district or non-public school subject to the provisions of 105 CMR 210.000;

(3) Any administration is pursuant to the order of a practitioner, and, in the case of first responders, and the Statewide Treatment Protocols.

(4) The epinephrine or nerve agent antidote is:

(a) dispensed by a pharmacy pursuant to the order or prescription of a practitioner or other authorized prescriber; or

(b) obtained by a municipality or agency in accordance with said entity's registration;

(5) The epinephrine or other antidote is packaged in a prefilled, automatic injection device intended for self-administration;

(6) A qualified, licensed practitioner shall be designated by the registered municipality or agency as medical director for purposes of 105 CMR 700.003(D).

Such person shall:

(a) be the responsible person named on the registration of the municipality or agency;

(b) authorize administration of epinephrine and nerve agent antidotes, as appropriate, and oversee compliance with 105 CMR 700.003(D);

(c) establish and enforce written protocols and procedures to ensure that individuals administering epinephrine or nerve agent antidotes are properly trained, evaluated for competence, and up to date in their skills and knowledge.

Training shall include, but not be limited to:

1. procedures for risk reduction;
2. recognition of the symptoms of a severe allergic or nerve agent reaction;
3. proper use of an auto-injector;
4. procedures for notification of emergency medical services and other appropriate persons following administration;

(d) establish and enforce written protocols and procedures to ensure:

1. proper storage, handling and return or disposal of epinephrine or nerve agent antidote;
2. review and evaluation of an emergency response;
3. reporting of adverse events to the medical director;
4. monitoring of program compliance with 105 CMR 700.003(D); and

(e) establish and enforce written protocols and procedures to ensure that a registered municipality or agency, or a program if authorized to administer epinephrine by a municipality or agency, maintains current and readily retrievable records of:

1. the authorized public employees or volunteers who may administer epinephrine and nerve agent antidotes or authorized program employees or volunteers who may administer epinephrine;
2. individual trainings and evaluations;
3. receipt and any return or disposal of epinephrine or nerve agent antidotes; and
4. administration of epinephrine or nerve agent antidote;

(7) Each program authorized by a registered municipality or agency to administer epinephrine pursuant to 105 CMR 700.003(D) shall:

(a) comply with the policies and procedures established pursuant to 105 CMR 700.003(D) by the registered municipality or agency;

(b) designate a licensed health care practitioner, whenever possible, or the program director or designee, to oversee the program's implementation of said policies and procedures;

(c) in the case of minors served by the program, obtain prior informed consent whenever possible from the minor's parent or legal guardian for the administration of epinephrine;

(d) develop individualized medication administration plans that address indications for administration of epinephrine, any unique issues around storage or handling of the epinephrine and persons to be notified in the event that epinephrine is administered; and

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(e) immediately notify emergency medical services and designated contact persons, including those identified in the medication plan, in the event that epinephrine is administered; and

(8) The registered municipality or agency, and the Department of Public Health, shall have full access to all pertinent records for monitoring purposes.

(E) A school district or private school may register solely for the purpose of permitting trained school personnel to administer controlled substances in accordance with 105 CMR 210.000.

(F) Employees of community programs may administer or assist in the administration of prescription medications to non-self-medicating persons, provided that:

(1) Registration. The community program is registered with the department in accordance with 105 CMR 700.004, and meets the following requirements:

(a) Administration or assistance in the administration of prescription medication to non-self-medicating clients shall be carried out only by duly licensed professional staff or by unlicensed program staff of registered community programs who have successfully completed the training specified in 105 CMR 700.003(F)(2);

(b) The program shall establish, maintain, and operate in accordance with policies which ensure that medication is administered only by properly trained and certified personnel;

(c) The program shall maintain a current written listing of those staff members who have successfully completed a training program meeting the requirements of 105 CMR 700.003(F)(2);

(d) The Department of Public Health shall be permitted by the program to inspect program and clients' records pertaining to the use and administration of prescription medications and is permitted announced or unannounced on-site visits or inspections of common areas and such other inspections as the Department of Public Health is authorized to make in order to monitor the program's compliance with 105 CMR 700.000.

(e) The Division of Food and Drugs within the Department of Public Health shall promptly be notified by the program of any suspected shortages or diversion of prescription medication;

(f) The program shall document in the client's record any administration of prescription medication in a manner inconsistent with the practitioner's prescription or in violation of 105 CMR 700.000. The program shall also promptly report to the Department of Mental Health or Department of Mental Retardation, as appropriate, on a form approved jointly by the Department of Public Health and said Departments, any administration of prescription medication in a manner inconsistent with the practitioner's prescription or in violation of 105 CMR 700.000 which staff has reason to believe created a risk of harm to the client. Such form shall be provided, upon request, to the Department of Public Health;

(g) The program shall provide or arrange for technical assistance and advice to be provided as needed by a Registered Nurse, Registered Pharmacist, or other Licensed Practitioner when questions arise regarding appropriate administration practices or the effects of medications. The program shall establish policies and procedures which ensure reasonable access to such assistance and advice;

(h) The program, professional staff and program staff shall comply with all applicable requirements of M.G.L. c. 94C, the Controlled Substances Act, as well as 105 CMR 700.000 and all pertinent regulations of the Department of Mental Health or Department of Mental Retardation, including those pertaining to storage, labeling, administration and documentation of prescription medication, medical back-up, review of medication, and emergency procedures.

(2) Training. No unlicensed staff person may administer or assist in the administration of prescription medications without successfully completing a training program which meets the specifications for a training curriculum and examination process established jointly by the Department of Public Health and the Department of Mental Health and/or the Department of Mental Retardation, as well as the following requirements:

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(a) The training program shall be taught by a registered nurse, nurse practitioner, physician assistant, pharmacist, or physician who meets applicable requirements for a trainer established jointly by the Department of Public Health and the Department of Mental Health and/or the Department of Mental Retardation;

(b) The Department of Public Health and, as appropriate, the Departments of Mental Health and Mental Retardation shall have the authority to monitor the training program for compliance with established standards;

(c) The training program shall keep records of all persons who have successfully completed the training program which shall be made available to the Department of Public Health and, as appropriate, to the Departments of Mental Health and Mental Retardation upon request;

(d) Each person who successfully completes the training shall be certified by the Department of Mental Health or the Department of Mental Retardation, as appropriate, and shall be provided with such documentation of completion of the training as approved by the Department of Mental Health and/or the Department of Mental Retardation. The original documentation of completion shall be provided to and maintained by the program;

(e) No person may continue to administer or assist in the administration of prescription medication beyond two years from the completion of the initial training unless such person has met standards for retraining and/or retesting established by the Department of Mental Health and/or the Department of Mental Retardation and approved by the Department of Public Health.

(3) Storage. The program meets all applicable Department of Mental Health or Department of Mental Retardation regulations as to storage and handling of prescription medications as well as the following requirements:

(a) All prescription medications which are consumed by clients who are non-self-medicating shall be kept in a locked container or area. The program shall have a written policy on which persons may have access to such container or area, how access to the key, combination and/or container or area is to be restricted, and under what conditions authorized persons may have access to the container or area;

(b) Prescription medications for clients who are self-medicating shall be stored in a locked container or area unless the program director makes a determination that unlocked storage of the prescription medication poses no threat to the health or safety of the client or other clients; provided, however, that all narcotics, tranquilizers and barbiturates shall be stored in a locked container or area;

(c) Outdated prescription medications and prescription medications which have not been administered due to a change in the prescription or a stop order shall be disposed of and the disposal documented in accordance with policies established by the program, provided that disposal occurs in the presence of at least two witnesses and in accordance with any policies of the Department of Public Health:

(4) Labeling. All medications are properly labeled in accordance with M.G.L. c. 94C, § 21 and the following requirements:

(a) Program staff shall not repack or relabel prescription medications which are taken or applied at any location or program regularly or frequently attended by the client. All such prescription medications shall be packed and labeled by a pharmacist or, in the case of prescription medication dispensed for immediate treatment, by the dispensing practitioner;

(b) Where prescription medication is consumed by a client at two or more locations on a regular or frequent basis, the prescription medication shall be stored in a separate, properly packaged and labeled medication container at each location. In circumstances where this is not practical or feasible, the Department of Mental Health and/or Department of Mental Retardation shall establish an alternative procedure approved by the Department of Public Health to be used.

(c) The program shall have policies for obtaining a properly labeled container where there is a change in prescription or where the client frequently or regularly receives prescription medication in two or more locations.

(5) Administration. All prescription medications are administered in accordance with M.G.L. c. 94C, applicable regulations for the Department of Mental Health or the Department of Mental Retardation and the following requirements:

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(a) All prescription medications shall be administered in accordance with the prescription of a practitioner;

(b) Prescribed medications shall only be administered to or taken by the person for whom the prescription has been written;

(c) The program shall have a policy which specifies the administrative procedures to be followed when there is a medical emergency relating to medication. Such policy shall include a list of staff persons and medical personnel to be contacted which is up to date, readily available to staff and clearly indicates who is to be contacted on a 24 hour a day, seven day a week basis. The medical personnel to be contacted shall include the prescribing practitioner or, if unavailable, another licensed practitioner or appropriate emergency room personnel;

(d) Certified staff employed by programs registered with the Department may only administer prescription medications which are oral, topical, ophthalmic, otic, internasal, suppository, or products which are administered by inhalation;

(e) Parenteral drugs generally intended for self administration, or drugs administered by gastric tube may be administered by staff members who have successfully completed a specialized training program in such technique taught by a physician, physician assistant, pharmacist, registered nurse, or nurse practitioner, approved by the Department of Public Health and/or the Departments of Mental Health or Mental Retardation. Such technique shall be used only with the written authorization and in accordance with the written instructions of the prescribing physician;

(f) Whenever possible, a prescription for medication shall be limited to a 30 day supply and one refill. The prescribing practitioner shall be notified by program staff of this requirement;

(g) Where a client who is non-self-medicating receives prescription medication at a location other than a program site covered by 105 CMR 700.000 (off-site), the program whenever possible shall identify an individual responsible for administering the medication and make available to that person instructions as to how the medication is to be administered;

(h) An over-the-counter drug may be consumed or applied by a non-self medicating client who is already receiving prescription medication only:

1. with the prior approval of a practitioner; or
2. after consultation with a pharmacist or registered nurse; or
3. in accordance with applicable guidelines established by the Department of Mental Health and/or the Department of Mental Retardation, with the approval of the Department of Public Health.

(6) Documentation. All prescriptions and administration of prescription medications shall be documented in accordance with applicable regulations of the Department of Mental Health or Department of Mental Retardation and the following requirements:

(a) All prescriptions for medication shall be noted in the client's record on medication and treatment forms developed by the Department of Mental Health and/or the Department of Mental Retardation and approved by the Department of Public Health. Such forms shall specify for each client the name and dosage of medication, the indication for which the medication is prescribed, and contraindications or possible allergic reactions, possible side effects and appropriate staff response, and special instructions, including steps to be taken if a dose is missed. The program shall establish appropriate policy and procedures to address how program staff shall obtain relevant prescription information in accordance with the requirements of 105 CMR 700.003(F)(6). In addition, such policy and procedures shall ensure that telephone medication orders and/or medication changes are received from licensed practitioners and properly documented in the client's record;

(b) The program shall ensure that staff have ready access to such information as listed in 105 CMR 700.003(F)(6)(a), by maintaining on site either an appropriate reference approved by the Department of Public Health or, for each drug administered, a copy of the pertinent section of such reference or a medication-specific drug information sheet which states in plain language generally why the drug is used, when it is to be administered, how it should be administered, any special instructions or precautions, proper storage conditions, possible side effects and what is to be done if a dose is missed;

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(c) The taking or applying of medications for non-self-medicating clients, including over the counter drugs, shall be documented in the client's medication and treatment forms;

1. the time that the medication is taken or applied shall be noted in the record;
2. the record shall indicate any off-site taking or applying of medication by a non-self-medicating client which would normally occur at the program site;
3. clients who are self-medicating shall not be required to document their own self-administration of medication;

(d) Any change in medications or dosage levels of a medication shall be treated as a new medication order for the purposes of documentation;

(e) A non-self-medicating client's residential program shall notify the client's day program of any prescription medications which the client is taking and shall provide the program with a copy of the medication and treatment forms meeting the requirements of 105 CMR 700.003(F)(6)(a) for each prescription medication which the client receives. Where a non-self-medicating client receives prescription medication solely at the day program, the day program shall have responsibility for notifying the residential program and providing it with a copy of the medication and treatment forms;

(f) The program shall establish procedures to document the date that any client's prescription is filled and the quantity of medication dispensed by the pharmacy;

(g) Except for persons who are self-medicating, the program shall maintain a documented accounting of the quantities of all controlled substance in schedules II through V, stored by the program, which shall be reconciled at the end of each shift or as otherwise approved by the Department.

(G) Optometrists may utilize and issue written prescriptions and medication orders, in accordance with the provisions of M.G.L. c. 112, §§ 66 and 66B, for those topical pharmaceutical agents in Schedule VI required for the diagnosis, prevention, management or treatment of abnormal ocular conditions or diseases as defined in M.G.L. c. 112, § 66, except glaucoma.

700.004: Registration Requirements

(A) Persons Required to Register. Every person who is required to be registered with the Commissioner under M.G.L. c. 94C shall register with said Commissioner as hereafter provided:

(1) Every person other than a registered retail drug business or wholesale druggist shall register if he:

(a) Manufactures, distributes, or dispenses any controlled substance, or

(b) Uses any controlled substance in research, teaching, or chemical analysis, or

(c) Possesses controlled substances with the intent to manufacture, distribute, or dispense any such substance, or

(d) Possesses controlled substances with the intent to conduct research, teaching or chemical analysis using any such substance.

(2) Persons required to be registered for controlled substances shall register separately for each one of the following business or professional activities applicable to him.

(a) Chemical Analyst
(b) Community Program
(c) Dentist
(d) Health Facility
(e) Manufacturer
(f) Physician
(g) Podiatrist
(h) Researcher
(i) Scientific Laboratory
(j) Teacher
(k) Veterinarian
(l) Ambulance Service/EFR Service
(m) School
(n) Physician Assistant
(o) Nurse Practitioner

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(p) Certified Nurse Midwife
(q) Psychiatric Nurse
(r) School District
(s) Private School
(t) Optometrist
(u) Municipality/non-municipal public agency

(3) A person involved in the qualitative or quantitative analysis of controlled substances within a scientific laboratory is required to register as an individual chemical analyst; in addition to the requirement that the scientific laboratory is also required to register.

(4) A hospital or other health facility is required to register if:

(a) It is not registered with the Board of Registration in Pharmacy and

(b) It possesses controlled substances which are safeguarded for or intended to be dispensed to any patient.

(5) A teacher in a teaching institution using controlled substances for instructional purposes is required to register, but the teaching institution is not required to register for teaching purposes.

(B) Exemptions from Requirement to Register. Persons primarily responsible for activities involving controlled substances in Massachusetts are required to register.

(1) Owners, partners and stockholders and parent corporations of registered businesses are exempted with regard to such ownership activities from the requirement to register.

(2) Persons exempted from the requirement to register by M.G.L. c. 94C are:

(a) An agent or employee of a registered manufacturer, distributor or dispenser acting in the usual course of his business or employment;

(b) A common or contract carrier or warehouseman or his employee, acting in his usual course of business or employment;

(c) A public official or law enforcement officer acting in the regular performance of his official duties.

(d) An ultimate user or research subject, at the direction of a practitioner in the course of his professional practice;

(e) A registered nurse or licensed practical nurse acting under the direction or authorization of a practitioner in the course of their professional practices.

(3) Any student enrolled in a school for nurses or practical nurses duly approved in accordance with M.G.L. c. 112, is exempted from the requirement to register when:

(a) Performing nursing services incidental to any prescribed course in such school, and

(b) Authorized or directed by a physician, dentist, podiatrist, veterinarian, certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant duly registered under 105 CMR 700.000.

(4) Certain persons engaged in interstate or foreign commerce are exempted from the requirement to register with respect to the exempted business activities only as follows:

(a) Vessels engaged in international trade or in trade between ocean ports of the United States.

(b) Aircraft operated by air carriers under a certificate or permit issued pursuant to the Federal Aviation Act of 1958.

(c) Persons who import controlled substances into the jurisdiction of the United States, and are in compliance with applicable Federal Law.

(d) Persons who export controlled substances from the jurisdiction of the United States, and are in compliance with applicable Federal law.

(5) An intern, fellow, medical officer, alien physician, registered nurse, licensed practical nurse, or other authorized person may dispense controlled substances under the registration of the hospital or other registered health facility by which he is employed and a "responsible person", as defined by the Department, may dispense controlled substances by ingestion only at the direction of a practitioner in the course of his professional practice, under the registration of the registered health facility by which such person is employed, in lieu of being registered himself provided that:

(a) He is authorized to dispense controlled substances in accordance with M.G.L. c. 112 if applicable, and

(b) Such dispensing is done in the usual course of his business or professional practice, and

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(c) The hospital or other registered health facility by whom he is employed has verified with the appropriate Board of Registration, if applicable, that the person is permitted to dispense controlled substances within Massachusetts, and

(d) Such person is acting only within the scope of his employment in the hospital or other registered health facility, and

(e) The hospital or other registered health facility authorizes the person to dispense controlled substances under the registration number of the hospital or other registered health facility and designates a specific internal code to consist of a numeric suffix to the health facility registration number preceded by a hyphen for each such person so authorized, and

(f) The hospital or other registered health facility maintains a current list of internal codes and makes such codes available at all times to other registrants, the Commissioner, and authorized law enforcement agencies.

(6) A registered pharmacist may dispense by administration influenza vaccine and other immunizations designated by the Department to persons 18 years of age or older provided that:

(a) Such registered pharmacist is authorized to dispense controlled substances in accordance with M.G.L. c. 112;

(b) Such administration is conducted pursuant to the order of a practitioner; and

(c) Such activity is conducted in accordance with guidelines adopted by the Department which shall include, but not be limited to, requirements for:

1. training accredited by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body; and
2. pre-administration education and screening;
3. vaccine storage and handling;
4. administration of medication, including administration of controlled substances as necessary for the management of medical emergencies;
5. record keeping; and
6. reporting of adverse events.

(C) Separate Registrations Required for Separate Activities. Each person shall obtain a separate registration for each group of activities in which he engages.

(1) A person engaged in one of the following business or professions shall be deemed to be registered only for the activities appropriate to that business or profession as follows:

(a) A person registered as a manufacturer is deemed to be
1. registered to manufacture controlled substances, and
2. registered to distribute controlled substances to registered persons.

(b) A person registered as a chemical analyst or scientific laboratory is deemed to be
1. registered to manufacture controlled substances, and
2. registered to conduct chemical analysis including quality control with respect to controlled substances, and
3. registered to distribute controlled substances to other registrants.

(c) A person registered as a teacher is deemed to be
1. registered to manufacture controlled substances, and
2. registered to conduct instructional activities with controlled substances.

(d) A registered physician, dentist, veterinarian, or podiatrist, registered by the appropriate Board of Registration is deemed to be registered to dispense controlled substances.

(e) A registered hospital, or other registered health facility is deemed to be registered to dispense controlled substances.

(f) A person registered as a researcher is deemed to be, within the scope of the protocol submitted to the Commissioner, if applicable,
1. registered to manufacture controlled substances, and
2. registered to distribute controlled substances to registered persons and
3. registered to conduct research with respect to controlled substances.

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(g) A registered ambulance service or EFR service shall only be registered to possess those controlled substances and instruments used to administer controlled substances, in quantity and in kind, that are necessary for pre-hospital emergency medical care in accordance with 105 CMR 170.000 and the Statewide Treatment Protocols and that are obtained fromthe hospital pharmacy, provided that auto-injectors containing epinephrine, atropine, pralidoxime chloride or other antidotes and medications approved by the Department may be obtained directly from the manufacturer or another source registered by the Department.

(h) A registered school is deemed to be registered solely in order to possess fluoride tablets and mouth rinse and to authorize fluoride program monitors and dental hygienists to administer fluoride tablets and mouth rinse in accordance with 105 CMR 700.000.

(i) A community program is registered for the sole purpose of authorizing its employees to administer or assist in the administration of controlled substances which are obtained from a pharmacy upon the prescription or order of a practitioner.

(j) A municipality or agency of the Commonwealth is registered for the purpose of authorizing possession and administration, in accordance with 105 CMR 700.003(D), of auto-injectors containing:

1 epinephrine for use by first responders and authorized employees and volunteers of a program operated, funded or licensed by the agency; and

2. epinephrine, atropine, pralidoxime chloride and other nerve agent antidotes approved by the Department for use by public employees and volunteers whose functions include emergency preparedness and response, including first responders.

(2) No person shall engage in any activities involving any controlled substance in any schedule for which he is not registered.

(D) Automatic Registrations. The Commissioner shall automatically issue a registration to dispense controlled substances other than for research pursuant to M.G.L. c. 94C, § 8, to any physician, dentist, podiatrist, or veterinarian who is duly authorized to practice his profession in the Commonwealth, provided that, any such physician, dentist, podiatrist, or veterinarian shall only be registered for Massachusetts Schedule VI and for the same schedules as he is registered with the Bureau of Narcotics and Dangerous Drugs.

(1) Any physician, dentist, podiatrist or veterinarian who is not registered with the Bureau of Narcotics and Dangerous Drugs shall be automatically registered to dispense controlled substances but only for Massachusetts Schedule VI.

(2) The Commissioner may periodically recall registrations to dispense controlled substances issued to practitioners, in accordance with M.G.L. c. 94C, § 7(f), and may issue a new registration upon verification that the practitioner continues to be duly authorized to practice his profession in Massachusetts.

(E) Time for Application and Term of Registration. No person required to be registered shall engage in any activity for which registration is required until he is registered for that activity.

(1) Any person who is registered with the Commissioner may apply to be re-registered on a form provided by the Commissioner not more than 60 days before the expiration date of his registration.

(2) Any registration issued by the Commissioner other than a registration to conduct research activities with Schedule I controlled substances or a registration to dispense automatically issued shall be effective for one year from the date of issuance.

(3) A registration issued to conduct research with Schedule I controlled substances shall be for such period, not to exceed one year, as may be specified by the Commissioner.

(4) Any person who is registered may at any time apply for a modification of his registration on a form supplied by the Commissioner.

(F) Separate Registrations Required for Separate Locations. A separate registration is required at each principal place of business or professional practice at one general physical location where the applicant or registrant manufactures, distributes or dispenses controlled substances, or uses controlled substances in research, teaching, or chemical analysis.

(1) The following locations are deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

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(a) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered.
(b) An office used by an agent of a registrant where sales of controlled substances are solicited, made or supervised but which neither contains such substances, nor serves as a distribution point for filling sales orders.
(c) An office or registered hospital or other registered health facility which is used by a physician, dentist, podiatrist, veterinarian, or optometrist who is registered at another location which is his principal place of professional practice, provided that no controlled substances are maintained by such practitioner at any place where he is not registered.

(G) Limitations on Registration for Schedule I. No person other than a person proposing to manufacture controlled substances in Schedule I; or a person proposing to conduct research on human beings involving controlled substances in Schedule I pursuant to M.G.L. c. 94C, § 8; or a person proposing to engage in qualitative or quantitative analysis of those controlled substances in Schedule I within a scientific laboratory shall be registered for activities involving the manufacture, distribution or dispensing of Schedule I controlled substances unless expressly authorized so to do by the Commissioner:

(1) Every applicant for registration for activities involving the manufacture, distribution or dispensing of controlled substances in Schedule I shall demonstrate to the satisfaction of the Commissioner, unless waived by the Commissioner:

(a) That he is registered by the Bureau of Narcotics and Dangerous Drugs specifically to manufacture, or conduct research involving, or to conduct chemical analysis with, controlled substances in Schedule I, and
(b) That he has never had an application denied or suspended or revoked by the Bureau of Narcotics and Dangerous Drugs or any predecessor agency for violation of any law or regulation and
(c) That his physical security controls are specifically approved by the Bureau of Narcotics and Dangerous Drugs, and
(d) That in the case of an application to conduct research with controlled substances in Schedule I his protocol is attached to his application and satisfies the requirements of 105 CMR 700.009(H).

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(H) Content and Form of Application. Each application for registration, renewal of a registration, or modification of a registration shall be on a form provided or approved by the Commissioner.

(1) The application form shall include:

(a) The applicant's name;

(b) The name and title of a responsible authorized representative of the applicant if the applicant is an institution, corporation, or other entity;

(c) The applicant's principal place of carrying on his or its business or profession;

(d) The applicant's business or professional activity for which he proposes to be registered;

(e) The schedules for which the applicant wishes to be registered; and

(f) The applicant's Bureau of Narcotics and Dangerous Drugs registration number, if any.

(g) The application of a certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant shall include the name and address of a supervising physician, a general description of the supervising physician's scope of practice, and the signature of the supervising physician. The certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant shall promptly notify the Department of any termination of employment, change of address, or change of supervising physician.

(2) The Commissioner may, in his judgement, require additional information.

(I) Application to Manufacture a New Controlled Substance. Any person who proposes to manufacture a controlled substance for which he is not registered with the Bureau of Narcotics and Dangerous Drugs, shall file with the Commissioner a copy of BND Form 130, which shall be treated as confidential by said Commissioner.

(1) He shall file a copy thereof at the time he files such form with the Bureau of Narcotics and Dangerous Drugs or before he begins manufacture, whichever is earlier.

(2) The applicant need not disclose any technical detail of the process which he regards as a trade secret but he must identify each substance used in or resulting from successive stages of manufacture, in order to notify the Commissioner of precursors and byproducts.

(J) Termination of Registration. The registration of any person shall terminate if and when such person dies or ceases legal existence or discontinues business or professional practice in Massachusetts or changes his name or address as shown on the registration, or has his registration revoked by the Commissioner.

(1) In the event of a change in name or address, the person may apply for a new registration in advance of the effective date of such change.

(2) Any registrant who ceases legal existence, or discontinues business or professional practice, or changes his name or address as shown on the Certificate of Registration shall notify the Commissioner at least 30 days before such event and shall surrender his Certificate of Registration by mailing it to the Commissioner on the day of such event.

(3) The executor of the estate of any deceased registrant shall surrender the deceased's Certificate of Registration by mailing it to the Commissioner as soon as feasible.

(K) Transfer of Registration Prohibited. No registration or any authority conferred thereby shall be assigned or otherwise transferred.

(L) Suspension or Revocation of Registration. The Commissioner may suspend or revoke a registration issued by him to manufacture distribute, dispense or possess a controlled substance:

(1) After a hearing pursuant to the provisions of M.G.L. c. 30A upon a finding that the registrant:

(a) Has furnished false or fraudulent material information in any application filed under the provisions of 105 CMR 700.000, or

(b) Has been convicted under any state or federal law of any criminal violation relating to his fitness to be registered under this chapter, or

(c) Has had his federal registration suspended or revoked to manufacture, distribute, dispense, administer or possess controlled substances, or

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(d) Is, upon good cause, found to be unfit or unqualified to manufacture, distribute, dispense or possess any controlled substance, or

(2) Pursuant to the provisions of M.G.L. c. 94C, § 13 for violation of any provision of M.G.L. c. 94C.

(M) Registration Number. The Massachusetts registration number of any person registered with the Bureau shall be the same as the registration number or one of the registration numbers assigned by said Bureau, as determined by the Commissioner.

(1) The Commissioner shall assign a Massachusetts registration number to any registrant not registered with the Bureau until such person is assigned a number by said Bureau, at which time the number assigned by the Commissioner automatically will become void.

(N) Registrations Effective as of July 1, 1972. Notwithstanding any other provision of these regulations, on and after July 1, 1972 a person shall be deemed to be registered with the Commissioner, until duly registered otherwise by the Commissioner or until the Commissioner informs him that he is not registered, or until August 31, 1972, whichever is earliest, provided that:

(1) If he holds at any time between July 1, 1972 and August 1, 1972 a valid registration issued by the Bureau, he shall be registered for the activities for which he is registered with said Bureau, for the Schedules for which he is registered with said Bureau, and for Massachusetts Schedule VI, or

(2) If he is a physician, dentist, podiatrist or veterinarian who is duly authorized to practice his profession in the Commonwealth and is not registered with the Bureau, he shall be registered to dispense Massachusetts Schedule VI other than for research pursuant to M.G.L. c. 94C, § 8, or

(3) If it is a health facility or part of a health facility which is licensed by the Department of the Department of Mental Health and possesses controlled substances which are safeguarded for or intended to be dispensed to any patient in such facility, in accordance with the regulations of the Department (105 CMR) or the Department of Mental Health (104 CMR), as applicable, it shall be registered to dispense controlled substances in accordance with such regulations.

700.005: Security Requirements

(A) Physical Security Requirements. All applicants and registrants shall provide effective physical security controls against theft and other diversion of controlled substances. All applicants and registrants shall provide physical security controls which meet the conditions of the Director of the Bureau of Narcotics and Dangerous Drugs.

(B) Personnel Security Requirements. All applicants and registrants shall screen before employment new employees who may work in or around areas where controlled substances are handled.

(1) Such screening shall be made solely for the purpose of determining whether the prospective employee is a responsible person. Documentation of such screening shall be made available by applicants and registrants to the Commissioner upon his request.

(2) No registrant shall knowingly employ any agent or employee who has had an application for registration denied for violation of any law or regulation or has had his registration revoked for violation of any law or regulation at any time.

(C) Security of Mail. Every registrant shall ensure that mail which can reasonably be believed to contain controlled substances and which is addressed to any person at the registrant's place of business or professional practice, is safeguarded until delivered directly to the addressee, or immediately returned to the sender.

(D) Report of Theft or Loss. A registrant shall report the theft or loss of any controlled substances to the designated agent of the Commissioner by telephone upon discovery of such theft or loss, and shall submit to said Commissioner a copy of "Report of Theft of Controlled Substances" (BND Form 106), within seven days of such theft or loss.

700.006: Requirements for Records, Inventories, and Reports

(A) Records Required, Generally. Every person registered with the Commissioner shall keep records, maintain inventories, and make reports in conformance with the requirements of the Federal "Comprehensive Drug Prevention and Control Act of 1970" or any amendment thereof and the Federal Food, Drug and Cosmetic Act, and with any additional regulations promulgated by the Commissioner.

(B) Time for Keeping Records. A registrant shall keep for at least two years from the date of preparation, every report, inventory and record he is required to keep by 105 CMR 700.000.

(C) Central Record Keeping. Any registrant may keep central records if he holds a valid permit to keep central records issued by the Bureau of Narcotics and Dangerous Drugs and notifies the Commissioner thereof.

(D) Exemptions from Record Keeping. A registered person who uses any controlled substance in research or teaching at a registered institution which maintains records, is exempt from the requirement to keep his own records, if he has notified the Bureau and the Commissioner of the name, address and registration number of the institution registered by the Bureau, which maintains his records; and a registered chemical analyst employed by a scientific laboratory which maintains records, is exempt from the requirement to keep his own records if he has notified the Commissioner of the name, address and registration number of the scientific laboratory which maintains his records.

(E) Inventory Requirements. Every registrant shall take an initial inventory and biennial inventories thereafter.

(1) Every registrant required to take inventories under Federal Law and Regulations shall follow those requirements, which are deemed to include Schedules I, II, III, IV, and V only.

(2) Every registrant who was not a registrant on August 1, 1972 and is not required to take inventories under Federal Law and Regulations shall take an initial inventory of all his controlled substances in Schedules I, II, and III on the day he first engages in the manufacture, distribution, or dispensing of controlled substances.

(3) Every registrant shall take a new inventory of all stocks of controlled substances in Schedules I, II, and III every two years following the date on which either the Federal or State initial inventory was taken, as applicable:

(a) On the day of the year on which the initial inventory was taken, or

(b) On the registrant's regular physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date and which would otherwise apply, or

(c) Any other fixed date which does not vary by more than six months from the biennial date which would otherwise apply.

(4) A registrant who elects to take his biennial inventory on his regular general physical inventory date or another fixed date, shall notify the Commissioner of this election and of the date on which he will take his biennial inventory.

(5) Whenever the Commissioner by regulation adds to any schedule a controlled substance which was not immediately prior to that date listed in a schedule on which a registrant was required to keep records, a registrant who possesses that substance shall:

(a) Take on the effective date of the regulation an inventory of all stocks of that substance on hand, and;

(b) Thereafter, include such substance in each inventory made by such registrant.

(F) Additional Records and Inventories Required of Practitioners. A registered physician, dentist, podiatrist, veterinarian, certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant shall maintain records and inventories in accordance with these regulations, with respect to all controlled substances in Schedules I, II, and III which he dispenses or administers in any manner, any exemptions for individual practitioners in Federal law and regulations notwithstanding.

700.006: continued

(1) A registered physician, dentist, podiatrist or veterinarian shall include in his inventories of controlled substances in Schedules I, II, and III the following information:

(a) For each controlled substance in finished form:

1. The name of the substance, and
2. The size of each finished form in metric weight or volume, and
3. The number of units or volume of each finished form.

(b) For each controlled substance not in finished form:

1. The name of the substance, and
2. The total quantity of the substance to the nearest metric unit of weight.

(2) Records maintained by registered physicians, dentists, podiatrists, certified nurse midwife, nurse practitioners, psychiatric nurse and physician assistants shall be closed to the public, and shall not be used in the criminal prosecution of any person in connection with his treatment as a patient by such physician, dentist, podiatrist, certified nurse midwife, and nurse practitioner, psychiatric nurse or physician assistant nor shall they be admissible in evidence against any such patient in connection with such treatment in any criminal, civil, legislative or administrative proceeding.

(3) Practitioner Records for Schedules I, II and III. A registered individual practitioner shall maintain on a current basis, separately for each registration he/she possesses, a complete and accurate record of each substance in Schedules I, II, and III received, distributed, administered, dispensed, and otherwise disposed of as follows:

(a) The name of the substance and the form of the substance, and

(b) The size of each finished form in metric weight or volume, and

(c) The number of units or volume of each finished form received from other persons; the date received; and the name, address, and Bureau registration number of the person from whom the substance was received, and

(d) The name, dosage and strength per dosage unit of each controlled substance administered or dispensed; the name and address of the person for whom the controlled substance was administered or dispensed and whether administered or dispensed by delivery or dispensed by prescription; the date of the administration or dispensing, and the written or typewritten name or initials of the person who administered or dispensed the substance, and

(e) The number of units or volume of such finished forms disposed of in any other way by the registrant, including the date and manner of disposal.

(4) Practitioner Records for Schedules IV and V. A registered individual practitioner shall maintain records, as described in 105 CMR 700.006(F)(3)(a) through (e), of controlled substances listed in Schedules IV and V which are dispensed, other than by prescribing or administering, in the lawful course of professional practice.

(5) Practitioner Records for Schedule VI. A registered individual practitioner, including an optometrist, who dispenses, other than by prescribing and administering, Schedule VI sample medications shall maintain a record, which may be kept in the patient's medical record, of the following information:

(a) the name, dosage and strength of the substance dispensed;

(b) the volume of units dispensed;

(c) the date of the dispensing; and

(d) the name and address of the person to whom the medication was dispensed.

(6) Record Keeping Requirements for Schools Registered for Fluoride Programs. Schools shall keep for a period of two years such records concerning the administration of fluoride tablets and mouthrinse as the Commissioner may require.

(G) Additional Reporting Required by Manufacturers. Each registered manufacturer shall submit to the Commissioner on forms approved or supplied by him, a quarterly report, on or before the 15th day of the month succeeding the period for which such report is submitted, accounting for all stocks of non-narcotic controlled substances appearing in Schedules I, II, and III on hand at the beginning and at the end of the quarter, and for all receipts, dispositions, manufacturing and packaging of such controlled substances. Such reports shall be made in a form as similar as possible to the Federal reporting requirements for narcotic controlled substances appearing in Schedules I, II, and III. Each registered manufacturer shall make available to the Commissioner the required Federal reports for narcotic controlled substances in schedules I, II, and III.

700.006: continued

(H) Distribution upon Discontinuance of Business or Professional Practice. Any registrant who desires to cease legal existence or discontinue business or professional practice or move his principal place of business or professional practice from the Commonwealth shall notify the Commissioner in writing at least 15 days before such event, and shall inform the Commissioner how he proposes to dispose of all the controlled substances in his possession. If the Commissioner does not notify the registrant by the date the registrant has proposed to dispose of such substances that he should postpone or cancel such disposal he may proceed as he proposed to the Commissioner. Any such registrant, any registrant whose registration has expired, the executor of the estate of any deceased person in possession of controlled substances, any registrant in possession of controlled substances which are safeguarded for or intended to be dispensed to any patient who has died, or been transferred from the jurisdiction of the registrant without such controlled substances being transferred, and any other person in possession of controlled substances for which he is not registered:

(1) Shall dispose of all controlled substances in his possession:

(a) Under the authorization and instructions of the Regional Director of the Bureau by transfer to a person registered to possess the controlled substances, or

(b) By delivery to an agent of the Bureau, or

(c) By delivery to an expressly authorized agent of the Commissioner, or

(d) By destruction of the substances in the presence of an agent of the Bureau, or

(e) By destruction of the substances in the presence of an expressly authorized agent of the Commissioner, or

(f) By such other means as said Regional Director may determine, and

(2) May transfer such controlled substances in accordance with 105 CMR 700.006(H)(1) without being registered to do so, and

(3) Upon the completion of such disposition, shall file with the Commissioner on a form approved or provided by him a final report of such disposition.

(I) Filing of Prescriptions by Pharmacies in Registered Health Facilities. Every pharmacy located in a health facility registered with the Commissioner shall file prescriptions for controlled substances as follows:

(1) Prescriptions for controlled substances listed in Schedules I and II shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedules I and II only;

(2) Prescriptions for controlled substances listed in Schedules III, IV, and V shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedule III, IV and V only; and

(3) Prescriptions for controlled substances listed in Schedule VI and prescriptions for non-controlled substances shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedule VI and non-controlled substances.

(J) Prescription Monitoring Program.

(1) Pharmacy Reporting Requirements.

(a) Every pharmacy located in a health facility registered with the Commissioner that dispenses controlled substances in Schedule II pursuant to a prescription, shall transmit to the Department or its agent the following information for each such prescription:

1. pharmacy prescription number;
2. pharmacy number (NABP);
3. patient identifier, where feasible;
4. date the controlled substance is dispensed;
5. metric quantity of controlled substance dispensed;
6. national drug code (NDC) of controlled substance dispensed;
7. estimated days supply of controlled substance dispensed; and
8. prescriber's U.S. Drug Enforcement Administration (DEA) registration number.

105 CMR 700.006(J) shall not apply to medication orders in hospitals.

700.006: continued

(b) The pharmacist shall make a good faith effort to verify the patient identifier of the person to whom the prescription for a controlled substance in Schedule II is delivered, in accordance with professional standards and personal judgment.

(c) The information required by 105 CMR 700.006(J) shall be transmitted to the Department or its agent no later than 15 days following the last day of the month in which the prescription was dispensed by use of:

1. electronic device, computer diskette, or magnetic tape, each in a format approved by the Department, or other acceptable electronic method approved by the Department; or,
2. Universal Claim Form.

(d) Pharmacies reporting data from 25 or more prescriptions in any given month must provide the required information in accordance with 105 CMR 700.006(J)(1)(c)1.

(e) The Department may grant a waiver to a pharmacy which is unable to transmit the required data in accordance with 105 CMR 700.006(J)(1)(c)1. for a period of 180 days, which 180 day period may be extended by the Department at its discretion. During the effective period of the waiver and any extension granted by the Department, the pharmacy must submit the required data in a format acceptable to the Department.

(2) Prescription Monitoring Program Advisory Board.

(a) The Commissioner of the Department of Public Health shall establish a Prescription Monitoring Program Advisory Board to assist in the implementation of 105 CMR 700.006(J) and any other related regulations. The membership of this Advisory Board shall include representatives of the Department of Public Health; Executive Office of Public Safety; disciplinary authorities, including the Boards of Medicine, Pharmacy, Dentistry, Podiatry, and Veterinary Medicine; representatives of associations or societies representing professions authorized to issue or dispense prescriptions, patient interests, and privacy interests; and a person with expertise in the design or operation of a secure automated data system.

(b) The Prescription Monitoring Program Advisory Board shall assist the Department in designing education programs for the proper use of Schedule II drugs.

(3) Prescription Monitoring Program Medical Review Group.

(a) The Commissioner shall establish Prescription Monitoring Program Medical Review Groups, to provide accepted medical practice standards for the implementation of 105 CMR 700.006(J) and related regulations. The membership of each Medical Review Group shall consist of two or more registered practitioners, one of whom shall be affiliated with a health care facility, and at least one registered pharmacist. In all cases, members of the Medical Review Groups shall be registered health care practitioners and a majority shall be registered in the same discipline as the practitioner whose records are under review. Registered practitioners shall be designated by the Commissioner from lists approved by the appropriate Boards of Registration in the discipline under which records will be reviewed. Such lists shall be provided by the respective statewide professional societies, whose membership shall fully represent the complete geographic and practice differences represented in the state as a whole.

1. In the event that insufficient listings are available to comprise the appropriate membership of any particular Medical Review Group, the Commissioner may appoint additional members.
2. Whenever possible, the practitioners on a particular Medical Review Group shall be specialists, as designated by a national accrediting board acceptable to the Commissioner, in the same field as the practitioner whose records are being reviewed.
3. In all cases, practitioners serving on the Medical Review Group must have a valid Controlled Substance Registration for prescribing Schedule II drugs, pursuant to M.G.L. c. 94C, § 18.

(b) The Medical Review Group shall assist the Department in the evaluation of prescription information.

700.006: continued

(4) Privacy and Confidentiality.

(a) Except where otherwise provided by law or judicial order, the information collected pursuant to 105 CMR 700.000 shall not be disseminated to anyone other than:

1. a duly authorized representative of the board or agency responsible for registration, regulation or discipline of practitioners authorized to prescribe or dispense schedule II controlled substances acting in accordance with their official duties;

2. a law enforcement agency when acting in accordance with its official duties in conducting a bona fide criminal investigation or prosecution of criminal violations. Requests for inspection of these records shall first be directed to the Office of the Attorney General of Massachusetts, or to the Massachusetts State Police Diversion Investigation Unit, or the United States Drug Enforcement Administration, for notification and approval prior to action by the Department;

3. an individual who is the data subject that has access to this data pursuant to a statute or regulation of the Commonwealth.

(b) All requests for information collected pursuant to 105 CMR 700.006(4)(a)2. must be in writing. All such information generated shall be reviewed and approved by the Commissioner and the Medical Review Group prior to release by the Department.

In the event that the Department, through computer analysis and review of the records generated by the prescription monitoring program, finds patterns of prescribing which raise questions regarding the behavior of patients, pharmacists or practitioners, the Department shall provide such information to the appropriate Medical Review Group for further review or referral, as provided for in 105 CMR 700.006(J)(4)(a)1. and 2.

700.007: Inspection of Premises

(A) Notice of Inspection Required. The Commissioner or any expressly authorized agent of his may carry out an inspection relating to any provision of the chapter of a registrant or applicant for registration, upon stating his purpose, presenting his appropriate credentials, and presenting a Notice of Inspection to the owner, operator or agent in charge of the premises to be inspected, if he is given in writing the informed consent of such owner, operator or agent in charge.

(B) Notice of Inspection Form. The Notice of Inspection Form shall be supplied by the Commissioner and shall contain:

(1) The name and title of the registrant.

(2) The name and title of the owner, operator or agent in charge if different from the registrant.

(3) The name, if any, and address of the controlled premises.

(4) The date and time of the inspection.

(5) A statement that the Notice of Inspection is given pursuant to M.G.L. c. 94C.

(6) A reproduction of the pertinent parts of M.G.L. c. 94C.

(7) The signature of the inspector.

(8) Provision for acknowledgment in writing by the owner, operator or agent in charge of the controlled premises that he has given his informed consent. Such acknowledgment shall contain a statement for the owner, operator or agent in charge that he has been informed:

(a) Of his constitutional right not to have an administrative inspection of the premises without an administrative inspection warrant;

(b) Of his right to refuse such an inspection;

(c) Of the possibility that anything of an incriminating nature which may be found may be used against him;

(d) That he has been presented with a Notice of Inspection in accordance with 105 CMR 700.000,

(e) That the consent given by him is voluntary and without threats of any kind; and

(f) That he may withdraw his consent at any time during the course of inspection.

700.007: continued

(C) Notice of Inspection Distribution. The Notice of Inspection and acknowledgment of informed consent shall be made in duplicate and one copy shall be retained by the Commissioner and the duplicate shall be given to the person inspected.

(D) Confidentiality of Trade Information. Unless the owner, operator, or agent in charge of a controlled premises so consents in writing, no inspection authorized by 105 CMR 700.000 shall extend to:

(1) Financial data, or
(2) Sales data, other than shipping data, or
(3) Pricing data, or
(4) Technical details of production processes other than as specified in 105 CMR 700.004(I): *Application to Manufacture a New Controlled Substance*.

700.008: Requirements Regarding Hypodermic Instruments

(A) License "to sell". No person except a registered physician, dentist, nurse, veterinarian, embalmer, pharmacist, wholesale druggist, or a registered podiatrist certified by the Board of Registration in Podiatry to be competent to use hypodermic needles, shall sell, offer for sale, deliver or have in possession with intent to sell hypodermic syringes, hypodermic needles or any instrument adapted for the administration of controlled substances by injection, unless licensed to do so by the Department.

(1) A license "to sell" shall be:
  (a) Valid for one year, and
  (b) Required at only one location for a company or corporation.
(2) The fee for a license "to sell" shall be $10.00.

(B) License "to purchase". No person except a registered physician, dentist, veterinarian, pharmacist, wholesale druggist, manufacturing pharmacist, pharmaceutical manufacturer, embalmer, or a manufacturer of or dealer in surgical supplies, official of any government agency requiring the use of such instrument by reason of his official duties, a nurse upon the written order of a physician or dentist, or a manufacturer of or dealer in embalming supplies, or a podiatrist certified by the Board of Registration in Podiatry to be competent to use hypodermic needles, a registered chemical analyst, an employee of a hospital or scientific institution upon the written order of its superintendent or an officer in immediate charge of a licensed person, a researcher registered pursuant to M.G.L. c. 94C, § 7, or a person who has received a written prescription to purchase a hypodermic instrument, shall obtain, receive, or purchase a hypodermic syringe, hypodermic needle or any instrument adapted for the administration of controlled substances by injection, unless licensed so to do by the Department or by a local board of health.

(1) A license "to purchase" issued by the Department shall be:
  (a) Valid for one year
  (b) Valid throughout the Commonwealth
(2) The fee for a license "to purchase" issued by the Department shall be $5.00.

(C) Application for License. A person who wishes to obtain a license to sell hypodermic instruments or a person who wishes to obtain a license issued by the Department to purchase hypodermic instruments, shall apply to the Department in an application form supplied or approved by the Commissioner:

(1) The application form shall indicate:
  (a) Whether the license is to sell, to purchase, or both, and
  (b) The 1. name, 2. address, 3. business or profession of the applicant, 4. purpose for which the applicant wishes the license, and 5. applicant's Bureau registration number, if any.

700.008: continued

(D) Extension of Licenses. Notwithstanding any other provisions of these regulations a license to sell, offer for sale, deliver, or be in possession with intent to sell hypodermic syringes, hypodermic needles, or any instrument adapted for the administration of controlled substances by injection, and any license to obtain, receive, or purchase a hypodermic syringe, hypodermic needle or any instrument adapted for the administration of a controlled substance, issued by the Department or by a local board of health on or before June 30, 1972, shall be deemed to be valid until the time it would have otherwise expired.

700.009: Research Involving Controlled Substances

Research projects and studies covered by M.G.L. c. 94C, § 8 shall be carried out in accordance with the regulations of the Commissioner.

(A) Persons Covered. No person, unless he supplies the Commissioner and the Commissioner of Mental Health (a) with satisfactory evidence of compliance with any applicable Federal law, and (b) with a protocol describing the research project or study to be undertaken if the Commissioner so requires shall carry out any research project, or study involving:

(1) Any narcotic drug in Schedule II or

(2) The investigational use on human beings of any new drug as defined in § 201(p) of the Federal Food, Drug and Cosmetics Act, as amended.

(B) Information to Be Submitted. The person immediately responsible for a research project or study covered by M.G.L. c. 94C, § 8, before commencing any such research project or study shall submit to the Commissioner and to the Commissioner of Mental Health:

(1) Satisfactory evidence of compliance with any applicable Federal law, as described in 105 CMR 700.009(C), and

(2) A proposed written "Statement of Informed Consent", and

(3) A statement of "Assurance of Compliance" with the requirements for the protection of human research subjects by an Institutional Review Committee, pursuant to 105 CMR 700.009(F) and 700.009(G), and

(4) A protocol describing the research project or study to be undertaken if the Commissioner so requires, and

(5) Such further information as the Commissioner, in his discretion may require.

(C) Evidence of Compliance with Applicable Federal Law. Satisfactory evidence or compliance with applicable Federal Law shall consist of:

(1) Any of the following which are required by the Federal Food and Drug Administration:

(a) Notice of Claimed Investigational Exemption for a New Drug (Form FD 1571); and

(b) Statement of Investigator (Clinical Pharmacology) (Form FD 1572); and

(c) Statement of Investigator (Form FD 1573); and

(2) A copy of the Bureau Registration of each person required to be registered by the Bureau.

(D) Protection of Human Subjects. No person shall undertake any research project or study covered by M.G.L. c. 94C, § 8 unless:

(1) The rights and welfare of all human subjects are adequately protected, and

(2) The risks to any human subject are outweighed by the potential benefits to him or by the potential benefits to mankind, and

(3) Every human subject has given his written "Statement of Informed Consent", by signing a written statement describing:

(a) The nature, duration and purpose of the investigation, and

(b) The method and means by which the investigation is to be conducted, and

(c) All inconveniences, hazards, discomforts, and risks reasonably to be expected, and

(d) The effects upon the subject's health or person which may reasonably be expected to come from his participation, and

700.009: continued

(e) A description of the controlled substances and other substances to be used, and their anticipated effects, side effects and interactions, and

(f) An identification of those procedures which are experimental, and

(g) A description of the benefits to be expected, and

(h) A disclosure of appropriate alternative procedures which would be advantageous to the subject, and

(i) An offer to answer any inquiries concerning the procedures, and

(j) An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.

(E) Statement of Informed Consent. Every written "Statement of Informed Consent" shall:

(1) Contain no exculpatory language, through which the subject is made to waive or appear to waive any of his legal rights or to release an institution or its agents from liability or negligence,

(2) Contain a statement for the subject to sign, that:

(a) He has read the "Statement of Informed Consent", and

(b) He understands the "Statement of Informed Consent" and the attendant risks described, and

(c) He understands he may terminate his consent at any time, and

(d) He voluntarily consents to be a research subject in the described project.

(3) Be obtained from the subject himself unless he is legally incompetent, in which case it may be obtained in writing from his legal representative, and

(4) Not be obtained in any event from a minor who refuses his consent.

(F) Assurance by Institutional Review Committee. No person shall undertake any research project unless an Institutional Review Committee:

(1) By majority vote with the record of the number in favor and the number opposed recorded, and by the signature of an authorized representative signifies its approval of:

(a) The protocol; and

(b) The "Statement of Informed Consent"; and

(2) Describes how it will monitor the person immediately responsible for the research project, including how and when such person will be required to:

(a) Submit written reports or

(b) Appear for interviews or

(c) Be visited by the Institutional Review Committee or its representatives, and

(3) Describes how it will notify the Commissioner regarding any:

(a) Proposed changes or

(b) Emergent problems, including significant hazards, contraindications and side effects.

(G) Institutional Review Committee.

(1) The Institutional Review Committee:

(a) May be an existing body, or

(b) May be specially constituted to review a research project.

(2) The Institutional Review Committee:

(a) Must exist in affiliation with the Department or the Department of Mental Health, or with a hospital licensed or maintained by the Department or the Department of Mental Health or the Commonwealth; and,

(b) Must be composed of at least five members with sufficiently varying backgrounds to assure complete and adequate review of any research project; and,

(c) Must include persons other than health professionals who have no business nor professional connection with such agency or hospital as not less than _ of its members; and,

(d) Must include documentation to identify the committee members by name, occupation or position, and by indications of experience and competence in areas pertinent to the areas of review.

(3) No member of such committee shall be involved in either the initial or continuing review of an activity in which he has a professional responsibility, except to provide information requested by the committee.

700.009: continued

(H) Protocol.

(1) The protocol shall describe:

(a) The identification and qualifications of the person in charge of the research project, and

(b) The objectives of the research project or study, and

(c) The procedures to be used, including:

1. The pertinent diagnostic classification or a description of the symptom or syndrome characteristics, of the human research subjects under investigation with a statement as to their general health status; and

2. The age range of the research subjects and whether one sex or both sexes will be used; and

3. Each specific controlled and any other substance which has not been approved by the Federal Food and Drug Administration for safety and effectiveness for use on humans to be used in the study; the forms in which the substances are supplied; and the methods by which the substances are to be administered or dispensed; and

4. The dosage range of each substance to be dispensed or administered, by either describing the specific dosage units, or the rate of administration, or the daily dosage regimens and the maximum period for which it will be dispensed or administered; and

5. The overall research design model to be employed; and

(d) The institutions or places where the project will be conducted or from which the substances will be dispensed or administered, and

(e) The projected period of time to complete the study, and

(f) The procedures to be used to ensure the security of the controlled substances; and

(g) Any other pertinent data or clarification which the Commissioner in his judgement may require or request.

(I) Requirement of Confidentiality. Records maintained by researchers, including every "Statement of Informed Consent", shall be closed to the public, and shall not be used in the criminal prosecution of any research subject in connection with his participation as a research subject, nor shall they be admissible in evidence against any such research subject in connection with such participation in any criminal, civil, legislative or administrative proceeding.

(J) Request to Inspect Protocol. If a request is made to inspect and/or release one of the protocols on file with the Department, the Department shall promptly notify the researcher and the pharmaceutical company(nies) sponsoring the clinical trial of the request, by telephone and followed up by written notification by certified mail. Such notification shall not include the identity of the person requesting inspection unless otherwise required by law, but may in the discretion of the Department include any known connection of the requesting party to organizations or entities with a competing commercial interest. In the case of a general request for inspection involving more than a specified researcher, protocol, drug or pharmaceutical company, and association representing pharmaceutical manufacturers and/or researchers may be notified in lieu of individual researchers and pharmaceutical manufacturers. Notification shall be at least eight calendar days prior to inspection.

700.010: Dispensing and Labeling of Sample Medications by Practitioners

(A) A registered individual practitioner may in the course of professional practice dispense to an ultimate user the following:

(1) A Schedule VI sample medication in a single dose or in such quantity as is in the opinion of the practitioner appropriate for the treatment of the patient but not exceeding a 30 day supply per dispensing; provided, however that this quantity may be increased to a 90 day supply if dispensed as part of an indigent patient drug program and deemed appropriate in the professional judgement of the practitioner;

(2) A Schedule II-V sample medication in a single dose or in such quantity as in the opinion of the practitioner is essential for the immediate treatment of the patient.

700.010: continued

(B) All sample medications dispensed by a registered individual practitioner shall be properly labeled.

(1) Whenever a sample medication is dispensed by a practitioner, a label shall be affixed to the outside of the package, and shall include the following information:

(a) practitioner's name and address;

(b) date of dispensing; and

(c) name of the patient, unless a veterinary product.

(2) In addition, the following information must be included on the label unless already provided for on the manufacturer's packaging of the sample medication:

(a) name, dosage form and strength of the sample medication;

(b) clear, simple and brief directions for use and any necessary cautionary statements; and

(c) date on which the medication will expire.

(3) Information provided to the patient under 105 CMR 700.010(B)(2) shall be, in the professional judgement of the practitioner, presented in a manner which can be easily understood by the patient. A combination of written information, labeling and counseling may be used to meet this requirement, based upon the individual needs of each patient.

(4) If multiple packages of the same sample medication are dispensed at the same time to the same patient, the samples may be placed in a larger container to which the label containing applicable information required by 105 CMR 700.010 has been affixed.

700.011: Issuance of Prescriptions or Medication Orders for Implantable Infusion Pumps Containing Schedule II or Schedule III Controlled Substance

A prescription or medication order for an implantable infusion pump containing a Schedule II or Schedule III controlled substance may be filled for a maximum of a 90 day supply.

700.020: Severability

The provisions of 105 CMR 700.000 are severable, and if any provision shall be in violation of any Federal rule or regulation or any Federal or Massachusetts law, such provision shall be null and void and such violation shall not affect or impair any of the remaining provisions.

REGULATORY AUTHORITY

105 CMR 700.000: M.G.L. c. 94C, § 2.